K092814

Section I
510(k) Summary

DEC 15 2009

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1. **Applicant's Name and Address**

Straumann US (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Telephone Number: 800-448-8168, ext 2513
Fax Number: 978-747-0023
Contact Person: Elaine Alan
Regulatory Affairs Specialist
Date of Submission: September 11, 2009

2. **Name of the Device**

Trade Name:	Straumann NC Temporary Abutments
Common Name:	Abutment, Dental, Endosseous implants
Classification Name:	Abutment, Dental, Endosseous implants
Regulation Number:	§872.3630

3. **Legally Marketed Device to which Equivalence is Claimed (Predicate Device)**

NC Temporary Abutments, K072679

4. **Description of the Device**

The Straumann Dental Implant System is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, permanent and temporary abutments and surgical and prosthetic parts and instruments. The devices covered in this submission are temporary abutments.

Abutments are placed on dental implants to provide support for dental restorations. Temporary abutments act as a basis for the fabrication of individual temporary restorations and temporary bridges on Straumann Dental Implants.

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5. **Intended Use of the Device**
The NC Temporary Abutments are intended for use with the Straumann Dental Implant for temporary restoration of single crowns and bridges.

6. **Technological Characteristics**
The proposed temporary abutments are substantially equivalent to the currently marketed devices. The intended use is **identical** to the predicate devices. The proposed abutment has the same material composition, basic design and fundamental operating principles to the currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Elaine Alan
Regulatory Affairs Specialist
Straumann Manufacturing, Incorporated
60 Minuteman Road
Andover, Massachusetts 01810

DEC 15 2009

Re: K092814
Trade/Device Name: Straumann NC Temporary Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 3, 2009
Received: December 4, 2009

Dear Ms. Alan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

K092814

Device Name: Straumann NC Temporary Abutments

Indications for Use:

The Straumann NC Temporary Abutments are indicated for use in Straumann NC Bone Level Implants for temporary restorations of single crowns and bridges for up to six months.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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RSBetz DDS for Dr. K P Mulroy (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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